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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,553	02/16/2001	Ming-Ming Zhou	2459-1-003 CIP	3124
23565	7590	02/24/2004	EXAMINER	
KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			LUCAS, ZACHARIAH	
			ART UNIT	PAPER NUMBER

1648

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/784,553

Applicant(s)

ZHOU ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Currently, claims 1-36 are pending in the action, claims 37-43 having been cancelled by the Preliminary Amendment filed on February 16, 2001. Pending claims 1-36 are subject to a Requirement for Restriction as indicated below.
2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-4, drawn to polynucleotides encoding peptides of 21-40 amino acids and comprising a ZA loop, classified in class 536, subclass 23.1.
 - II. Claims 5-8, drawn to peptides of 21-40 amino acids and comprising a ZA loop, classified in class 530, subclass 300.
 - III. Claims 9-10, drawn to antibodies to the peptides of Group II above, classified in class 530, subclass 387.1.
 - IV. Claims 11, 12, 14, 15, 25, 26, and 28, drawn to methods of identifying promoters of a bromodomain (including P/CAF) binding to a protein (including Tat with an acetylated Lysine at position 50 of SEQ ID NO: 45), classified in class 435, subclass 7.1.
 - V. Claims 11, 13, 14, 15, 25, 27, and 28, drawn to methods of identifying inhibitors of a bromodomain (including P/CAF) binding to a protein (including Tat with an acetylated Lysine at position 50 of SEQ ID NO: 45), classified in class 435, subclass 7.1.

- VI. Claims 16, 17, 19, 20, 30, 31, and 33, drawn to methods of identifying stabilizers of a bromodomain-ligand binding complex (including a P/CAF-Tat complex wherein the Tat has an acetylated Lysine at position 50 of SEQ ID NO: 45), classified in class 435, subclass 7.1.
- VII. Claims 16, 18, 19, 20, 30, 32, and 33, drawn to methods of identifying inhibitors of a bromodomain-ligand binding complex (including a P/CAF-Tat complex wherein the Tat has an acetylated Lysine at position 50 of SEQ ID NO: 45) by measuring stability of the complex in the presence of the agent, classified in class 435, subclass 7.1.
- VIII. Claims 21-22, drawn to methods of identifying binding partners for a protein comprising an acetyl-lysine, classified in class 435, subclass 7.1.
- IX. Claim 23, drawn to agents that inhibit binding of bromodomains with a protein, said agent selected from SEQ ID NO: 4, 5, or 6, classified in class 514, subclass 1.
- X. Claim 24, drawn to a computer with a representation of a Tat-P/CAF complex, classified in class 703, subclass 11.
- XI. Claims 29, and 35 drawn to promoters of P/CAF binding to Tat, classified in class 514, subclass 1.
- XII. Claims 29, 35, and 36, drawn to inhibitors of P/CAF binding to Tat, classified in class 514, subclass 1.
- XIII. Claims 34, and 35, drawn to compounds that stabilize the complex of Tat and P/CAF, classified in class 514, subclass 1.

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XIV. Claims 34, 35, and 36, drawn to compounds that destabilize the complex of Tat and P/CAF, classified in class 514, subclass 1.

For Group I above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-XIV, and, if Group I is elected, then election is also required to one of subgroups A, B, or C. The inventions of these subgroups represent the invention of the elected Group wherein:

- A) the peptide comprises an amino acid sequence of SEQ ID NO: 3 (Note- if the Applicant elects this subgroup, applicant is required to elect a specific sequence to be searched);
- B) the peptide comprises an amino acid sequence of SEQ ID NO: 48 (Note- if the Applicant elects this subgroup, applicant is required to elect a specific sequence to be searched); or
- C) the peptide comprises one of the sequences of SEQ ID NOs: 7-42 (Note- if the Applicant elects this subgroup, applicant is required to elect a specific sequence to be searched).

For Groups II and III above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-XIV, and, if one of Groups II or III is elected, then election is also required to one of subgroups A or C as described above with reference to Group I.

For Groups IV-VII above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-XIV, and, if one of Groups IV-VII is elected, then election is also required to one of subgroups D or E. Subgroups D or E represent the elected method, wherein:

- D) the compound being tested is selected using rational drug design from the information of Tables 1-6; or
- E) the compound being tested is selected using rational drug design based on the coordinates of the three-dimensional structure of a bromodomain consisting of SEQ ID NO: 7.

For Group VIII above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-XIV, and, if Group VIII is elected, then election is also required to one of subgroups in subgroup C above.

For Group IX above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-XIV, and, if Group IX is elected, then election is also required to one of subgroups F-H. Subgroups F-H represent the elected invention wherein the agent inhibits the binding between a bromodomain and peptides comprising the sequence of:

- F) SEQ ID NO: 4;

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G) SEQ ID NO: 5; or

H) SEQ ID NO: 6.

The inventions are distinct, each from the other because of the following reasons:

3. The inventions of Subgroups A-C, and F-H are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions relate to different proteins with different structures, and that therefore have different modes of operation.
4. The inventions of Subgroups D and E are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions relate to different modes of identifying compounds. Because these groups have different modes of operation, they are distinct.
5. The inventions of Groups I, II, III, IX-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions each perform different functions, and have different structures from the inventions of the other Groups. Further, each of these compounds has a different mode of operation and a different effect from such other inventions.
6. The inventions of Groups IV-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions the different methods each relate to a method for the

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identification of a compound that performs a different function. Because the different methods are useful for the identification of different compounds, they each perform a different function. They are therefore distinct.

7. The inventions of Group I and of Groups IV to VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the peptides may be used in methods other than those disclosed. Aside from being useful in any of the claimed methods, the peptides are also useful for the making of antibodies. The inventions are therefore distinct.

Conclusion

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. It is here noted that some of the restrictions requirements made above fall within the scope of PTO Linking claim practice. In accordance with this practice as described in MPEP 809.03, linking claims will be considered with the elected invention. If the elected invention is found allowable, the linking claim will also be examined. If no substantive rejection is found for the linking claim, the restriction among the Groups it comprises will be withdrawn.

Claims 11 and 25 are linking claims for the inventions of Groups IV and V.

Claims 16 and 30 are linking claims for the inventions of Groups VI and VII.

Claim 29 is a linking claim to the inventions of Groups XI and XII.

Claim 34 is a linking claim to the inventions of Groups XIII and XIV.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

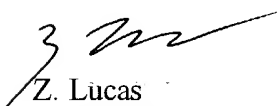
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


JAMES HOUSEL 3/28/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1648